

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

0108 '00 FEB 17 A9:03

**Food and Drug Administration**

*QES DMB*

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*1903*

**General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on March 1, 2, and 3, 2000, 8 a.m. to 5 p.m.

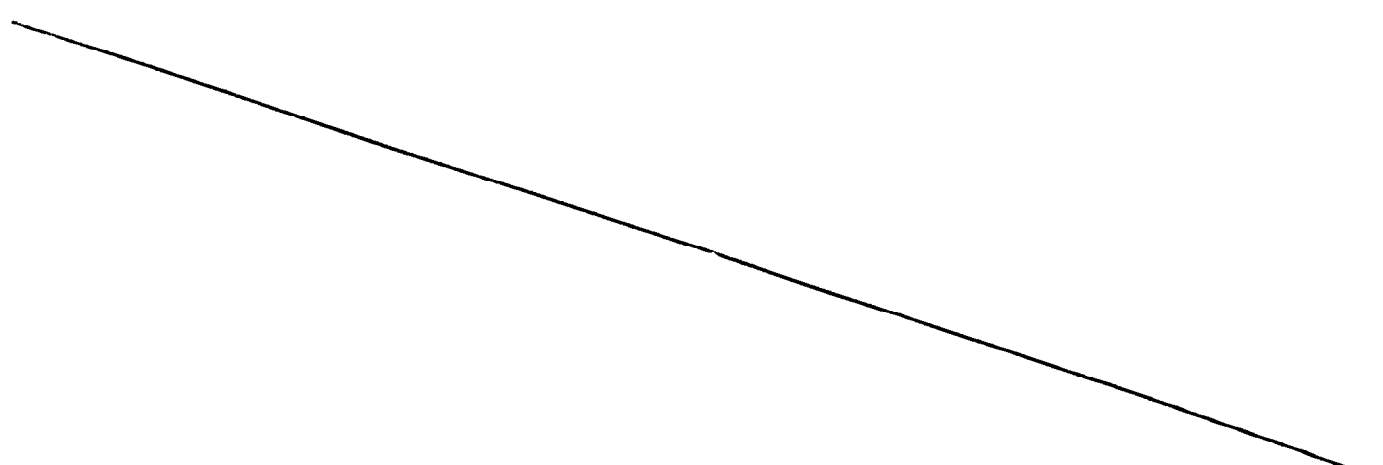
*Location:* Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person:* David Krause, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090, ext. 141, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12519. Please call the Information Line or access the Internet address of <http://www.fda.gov/cdrh/panelmtg.html> for up-to-date information on this meeting.

*Agenda:* On March 1, 2000, there will be a brief FDA presentation on the least burdensome provisions of the FDA Modernization Act of 1997. Also, on March 1, 2000, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for saline inflatable breast prostheses. On March 2, 2000, the committee will discuss, make recommendations, and vote on two PMA's for saline inflatable breast prostheses. These PMA's have been submitted

in response to a call for PMA's under section 515(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 306e(b)), published in the **Federal Register** of August 19, 1999 (64 FR 45155). On March 3, 2000, the committee will discuss content, format, and consistency issues involving the labeling information provided to patients considering saline-filled breast prostheses. The document entitled "Guidance on Medical Device Patient Labeling" is the background information for the panel discussion and is available to the public on the Internet at <http://www.fda.gov/cdrh/HumanFactors.html> or CDRH Facts-on-Demand at 1-800-899-0381 or 301-827-0111, specify number 1128 when prompted for the document shelf number. As it becomes available, additional information specific to saline breast implants will be available to the public on FDA's website at <http://www.fda.gov/ohrms/dockets/ac/00mtbc.htm>.

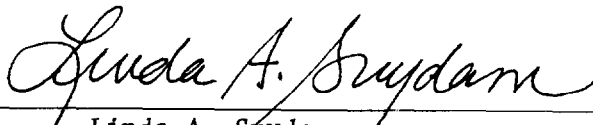
*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 23, 2000. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 12 noon, and 3:45 p.m. and 4:15 p.m. on March 1, 2000; between approximately 8 a.m. and 8:30 a.m., 11:15 a.m. and 11:45 a.m., 1 p.m. and 1:30 p.m., and 4:15 p.m. and 4:45 p.m. on March 2, 2000; and between approximately 9:15 a.m. and 11:15 a.m., and 2:45 p.m. and 3:15 p.m. on March 3, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 23, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 2/14/00  
February 14, 2000



Linda A. Suydam  
Senior Associate Commissioner

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

**BILLING CODE 4160-01-F**

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**

